

**Claim Rejections -35 USC § 112**

The outstanding Office Action indicates that Claims 1-3, 6-11 and 15-26 (all of the pending claims) are rejected under 35 USC § 112. The basis of the objection focuses upon the alleged vagueness of the phrase "pentagonal dodecahedral" and the recited dimensions ("wherein at least one dimension is less than 10nm") of this structure. As to the phrase to "pentagonal dodecahedral", this phrase refers to the three-dimensional shape/geometry of the water cluster, having a water ( $H_2O$ ) molecule at each of the 20 vertices of the dodecahedron as depicted in Figures 7 and 9. Thus these terms and depictions define the shape/geometry of the water cluster as well as representing the number of water molecules (typically 20) defining the boundary of this cluster. Additionally, the Examiner attention is directed to United States Patent No.5, 800,576 which was incorporated herein by reference, particularly Figure 10 which shows a 20-molecule pentagonal dodecahedral water cluster, the discussion of this figure beginning at Col. 5, line 41 and the other discussion of pentagonal dodecahedral water clusters beginning at Col. 6, line 6. It is believed that the Examiner's perceived lack of clarity on this point may be based in part be due to a failure to recognize that in the current specification, the 20-molecule pentagonal dodecahedral water nanocluster cluster depicted in Figure 2 is a two-dimensional projection of the 20-molecule cluster and therefore only appears to have 10 molecules. In a perspective drawing (of the type depicted in the chains of dodecahedral water clusters shown in Figures 7 and 9), the 20 water molecules of the pentagonal dodecahedron are readily evident. It is also noted for completeness, that the 20  $H_2O$  molecules form a dodecahedral "cage" that can harbor other molecules such as a hydronium ion  $H_3O^+$ , resulting effectively in a dodecahedral cluster with 21  $H_2O$  molecules plus a proton.

As to the dimension of the pentagonal dodecahedral cluster, as discussed above, the clusters claimed herein are of three-dimensional shape/geometry which form an approximately spherical cluster. The recited dimensions are relevant to and appropriately describe an approximately spherical shape. As more fully discussed in Applicant's specification (e.g., at Page 8, line 21 to Page 9, line 13), the less than 10 nm dimension water nanoclusters claimed herein may spherical with a 0.8 nm dimension, a five water cluster needle-like array in which the structure is needle-

like with one dimension of about 0.8 nm and a length of 3 nm, etc.

It is respectfully submitted that both the phase "pentagonal dodecahedral" and recitation of the dimensions thereof are clear to one skilled in this art, and the recitation thereof in Claims 1-3, 6-11 and 15-24 are not vague or indefinite under 35 USC § 112 and it is urged that this rejection be withdrawn. It is further noted that the rejection as to Claims 25-26 is even more clearly improper in that the phases does not even appear in these claims.

#### **Claim Rejections -35 USC § 103(a)**

The outstanding Office Action indicates that Claims 1-3, 6-11 and 15-26 are rejected under 35 USC 103(a) as being unpatentable over EP 0916621 by itself and further in view of Lorenzen (U.S. Patent No. 5,711,950) ("Lorenzen"). Applicant respectfully traverses this rejection, for the reasons previously set forth and as set forth below.

Several of the Examiner's comments in this presenting this rejection focus upon what water clusters are, the relevant properties thereof and how the teaching in the cited references allegedly relate thereto. In view of this, Applicant believes that it would be helpful to briefly summarize the background of this invention, as set forth in the specification, to help assure a clearer understanding of the invention as claimed and the distinctions from the cited references, as follows:

The present invention provides water nanocluster/oil compositions and methods for delivery of water clusters to the skin. As stated in the process claims, the composition is delivered "through the outermost layer of human skin". The water nanoclusters have at least one dimension of less than about 10 nanometers and specific embodiments are more specifically characterized as to the cluster's size (e.g., 0.8 nm or less) and the cluster's form (e.g., needle-like arrays, discussed at Page 3 line 16 to Page 4, line 16). The water clusters will be present in the oil as a water-in-oil (w/o) emulsion, wherein oil is the continuous phase and water is dispersed therein (see, e.g., Page 8, line 21 et seq.), as distinct from being in the form of the oil in water (o/w) emulsions (which are the common form of commercially produced cosmetic products). In a w/o emulsion, the oil is dispersed in the water (i.e., water is

the continuous phase).

Turning now specifically to the references cited in the rejection, the Applicant understands the Examiner's position on EP 0916621 (from the statements at Page 3 of Office Action in stating the rejection and Page 5-6 of the Office Act is the "Responding to Arguments" section) to essentially be: (1) the reference's fine clustered water is the same as the water nanoclusters herein, (2) the reference's fine clustered water are produced by the same processes as the water nanoclusters herein, (3) the reference teaches the same water-in-oil (W/O) emulsions as herein and (4) the reference teaches the same absorbability /delivery to the skin as the process herein. It is respectfully submitted that the Examiner has not demonstrated this points as follows:

(1) As to whether the fine clustered water is the same as the water nanoclusters, as previously pointed out, EP 0916621 defines the terms "pure water" (as a specific resistance of 50 or less) and "cluster" (as an "aggregate of molecules" are defined at Page 3, lines 15-20). However, importantly, the term "fine" is neither defined nor quantified by example or otherwise. The closest teaching to a "definition" in the reference appears in the statement at Page 3, lines 19-20, namely, "In the present specification, a fine clustering treatment means reducing the size of the cluster." However, this does not provide any reasonable definition or quantification of "fine" even assuming that the starting point (how many molecules of water were in the starting water cluster) was specified, but it is not. Further, the present invention in Claims 1-3, 6-11 and 15-24 does not merely use the terms water nanoclusters, but further specifies that the cluster are pentagonal dodecahedral as well as having at least one dimension less than about 10 nm.

Further, not only is the term "fine-clustered" not defined in EP 0916621, but also there is no specification of the shape/geometry thereof, whereas the pentagonal dodecahedral water clusters herein e.g., as shown in Figure 1 and "needle-like" arrays of such water clusters as shown in Figure 7), are precisely defined shape- and size-wise. Only pentagonal dodecahedral water clusters (e.g., as shown in Figure 2 and arrays thereof as shown in Figure 7) in water-in-oil (w/o) nanoemulsions possesses the protruding π molecular orbitals (as is discussed and depicted in United States Patent No.5,800,576) that will produce antioxidant

properties capable of reducing cell damage without the need for externally added antioxidants. Perhaps, in view of the Examiner questions about the meaning of these terms, she did not consider these claimed/structural elements, but they are importantly specified in the claims and are not taught or suggested by the reference.

(2) As to the whether the reference's fine clustered water are produced by the same processes as the water nanoclusters herein, the reference's described process for producing its "fine clustered water" range from the use of magnetic fields, to electric currents, to mechanical, to ultrasonics, etc. (see Page 3, line 30 to Page 4, line 52) which could produce vastly different "reducing of size", even assuming that the starting point (how many molecules of water were in the starting water cluster) were specified, but it is not. The only treatment approach specifically exemplified is the "magnetic method" which involves passing the water through a "slit" between magnetic plates, with the slit size stated to be "not limited", but preferably "about 2 mm" from which one might conclude that the water clusters were of that mm dimension (see Page 4, lines 15-42). This does not teach either the size of the clusters or the structure form thereof, both of which are specified herein. Perhaps some of these methods "might" under appropriate design and conditions do so, but the form/size of the water nanoclusters specified herein is neither specified nor necessarily/inherently produced. It is true that the present specification indicates that the water nanoclusters of the present invention can be produced by a variety of means in addition to the specifically exemplified use of surfactants which is most preferred (see Page 4, lines 26-30). This invention does not claim the specified water nanoclusters *per se* or the first manufacture thereof. But that is a far cry from suggesting that the "shopping list" of various generically described methods of making "fine clusters" mentioned in by EP 0916621, produces the highly specific and unique water nanoclusters of this invention. EP 0916621 does not even mention these unique structures and would not teach, suggest or motivate anyone to select the necessary design and conditions within these methods to do so.

(3) As to the type of emulsion taught by EP 0916621, the reference is directed to the uses of water as a dispersing media and deals with the stated difficulties of dissolving or dispersing substances in water without using a solvent or detergent. A dispersing media creates the

continuous phase of an emulsion in which something else is dispersed. In this reference, water is the dispersing media and with oil in the dispersed phase, you have an oil-in-water (O/W) emulsion, not a water-in-oil (W/O) emulsion as specified herein. Applicant notes the Examiner assertions that the reference teaches W/O emulsions, but reading the reference as a whole (not merely the references "invention" or "problems" encountered as the Examiner suggested was done in Applicant's Response), such a teaching is absent. To the contrary, EP 0916621 consistently describes in its specification including its examples, that use of its "fine" clustered water" to improves the solubility or dispersing ability of oil and fats in the water, beginning in the Abstract stating that its fine clustered water "is able to disperse at least about 1.5 times as much glyceryl trioleate as purified water"); in the Field of the Invention ("relates to water which has a superior ability to disperse oil and fats."), in its Description of the Related Art (...water is mainly used as a solvent) and in its Examples(e.g., Example 1, "The concentration of the dispersed glyceryl trioleate in the water ... )as well as in all of its Claims ( water ... able to disperse). Clearly, the emulsions taught or suggested in EP 0916621 are oil-in-water (O/W) emulsions -- water is the dispersant and the oils/fats are the dispersed phase --, which is distinctly different than the - water-in-oil (W/O) emulsions of the present invention. It is respectfully submitted that the Examiner statement that EP 0916621 teaches the "water-in-oil emulsions" is without support.

(4) As to the whether the reference teaches the same absorbability /delivery to the skin as the process herein, the Examiner states that EP 0916621 teaches that its "clustered water improves the absorbability of the dissolved substance and is a good delivery vehicle See page 5, lines 5-7". As discussed above, the reference teaches the use of water to improve the delivery of the dispersed substance (e.g., as stated at Page 5, lines 4-6 of the reference, and that "The fine-clustered water from pure water of the present invention has not only a high dispersing ability of oil and fats, but also improves the absorbability of a dissolved or dispersed substance..."). Importantly, all the reference is teaching in that the dispersed material can be delivered to the skin and be better absorbed (presumably better of its more dispersed form), but this says nothing about the water's dermal penetrability. Contra distinctly in the present invention,

the process involves delivery "through the outermost layer of human skin". The specified water clusters in the w/o emulsion of the present invention provide important advantages when applied to the skin, due to (1) their ability (based upon the quantum chemistry-computations and other reasons discussed at Page 10, lines 1-24) to pass through the outermost layer of the skin and (2) the unique properties (including anti-oxidant benefits) from the water nanoclusters *per se* (see, e.g., Page 10, line 11 to Page 11, line 14. In particular, the unique shape/geometry form of the water clusters of this invention (as described above) provide water-cluster surface pΠ electron donating orbitals which are capable of donating electrons to cell-destroying free radicals, in a manner similar to that believed to be associated the pΠ electron orbitals of Vitamin E. As explained at Page 9, lines 24 to Page 10, line 24, the present invention's process for delivery of the specified water nanoclusters through the outer most layer of the skin (the stratum corneum) allows the water nanoclusters beneficial effects and other ingredients in the formulations to be delivered transdermally. As shown in Applicant's specification in comparative Example 5, the percent of transdermal transport of a formulation of the present invention (produced per Example 1, far exceeds (e.g., 41 % vs.14% after 10 hours) the transport of a the formulation of Example 4, which differs in that the water is not in the form of nanosized micelles specified in the present invention. The Examiner statement that EP 0916621 teaches the "advantages of microclustered water" is without any support and improper particularly if intended to suggest that the reference suggests use of the specific water clusters taught by the present invention.

In view of the above, it is respectfully submitted that the rejection over EP 0916621 by itself is clearly unfounded and should be withdrawn

As to EP 0916621 in combination with the Lorenzen patent, the Examiner states that the reference (EP 0916621) "does not specify the size of the water clusters" and then goes on to describe how this deficiency is allegedly overcome by the Lorenzen patent. As noted above, the "size of the water clusters" is not the only deficiency of EP 0916621. However, Applicant will focus upon this issue in response.

The entire thrust of the EP 0916621 is that the fine

water is an improved dispersing media (i.e., water is the continuous phase which is the case in a O/W emulsion with the oil being the dispersed phase). Importantly, the absence of any definition or quantification in EP 0916621 of "fine" is not only an absence of a teaching of an important element of the present invention, it can only be reasonably interpreted to mean that the reference used this term in a non-specific qualitative sense, especially since the reference did specifically define or quantify other terms. There is no indication in the reference whatsoever of any need to go to a specific form or degree of "fine" clusters. The only reasonable inference in that the specific size or form or degree of "fine" clusters is not important to the practice of EP 0916621's teaching, and there would be no reason, direction or motivation to look to other teachings of water clusters.

However, assuming arguendo that one would motivated (and Applicant's position is that one would not) to look to other teachings of the "fineness" of water, Lorenzen does discuss the preparation of "microclustered water" and alleges that the clusters include 3-15 molecules would not provide a sufficient teaching. Clearly, Lorenzen's teaching does not address the water nanoclusters of the present invention. The present invention is not directed to Lorenzen's 3-15 molecule "microclusters", but instead pentagonal dodecahedral water nanoclusters of specified dimensions. As discussed above, these unique structures have water ( $H_2O$ ) molecules at each of the 20 vertices of the dodecahedron. In fact, Lorenzen teaches away from the use of such larger clusters (e.g., such as the 20 water molecule structures) by stating (at Column 8, lines 53-54) that "Larger clusters are believed to have a lower biomedical effect."

Still further, it is important to note that Lorenzen's alleged biomedical effect is based upon the "template" which is defined at Col 1, 47-51 as "any material which is used with microclustered water to create a molecular structure therein for the achievement of the specific results" with the inventor further stating "I believe that that the microcluster technology described herein can be applied to virtually any template to import the properties of the template into the resulting microclustered water" (Col. 8, lines 42-46. As such, Lorenzen is allegedly providing a form of water which is a better vehicle for delivery of the functional template substance, not

ascribing or suggesting any beneficial biological properties to the water *per se*.

As noted above, only concatenated pentagonal dodecahedral water clusters (as shown in Figure 2 herein) and arrays thereof (as shown in Figure 7 herein) in water-in-oil (W/O) nanoemulsions possess the protruding pπ molecular orbitals that will produce antioxidant properties capable of reducing cell damage without the need for externally added antioxidants. There is no teaching or reason to believe that the 3-15 molecule arrangements claimed by Lorenzen exhibit such properties.

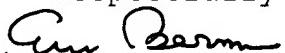
It is respectfully submitted that EP 0916621 is improperly combined with Lorenzen and even it were, the references do not in combination teach or suggest the present invention.

The foregoing remarks apply to each of the process and composition claims pending in the application. Additional specific basis for allowance exist as to individual claims. For example, the cited references do not alone or in combination teach or suggest: the needle-like form specified in Claim 16; the reverse micelle structure specified in Claim 17; the needle cavity resulting in cylindrical for the water nanoclusters set forth in various of the claims. None of these important distinctions were noted in Office Action.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action in accordance thereof is requested.

In the event there is any reason why the application cannot be allowed in this current condition, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems by Interview or Examiner's Amendment.

Respectfully Submitted,



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